VIRGINIA BOARD OF PHARMACY
6603 West Broad Street, Fifth Floor
Richmond, Virginia 23230-1712
804-662-9911

REGULATORY INFORMATION FOR NEW PHARMACIES

REVISED August 2005

The complete Drug Control Act and Regulations of the Board of Pharmacy can be accessed at our website: www.dhp.virginia.gov.

To apply for the Drug Enforcement Administration (DEA) Registration, please contact DEA at:

Drug Enforcement Administration
Techworld Plaza
800 K Street, N.W., Suite 500
Washington, D.C. 20001
202/305-8888

DEA will accept and process an application prior to a permit being issued from the Board of Pharmacy; however, it will not issue a registration or number until the pharmacy has been inspected, approved, and issued the pharmacy permit by the Board of Pharmacy.

Notes:

Please note that Regulation 18 VAC 110-20-180 requires that the alarm device must detect breaking by any means when activated and must be approved prior to stocking drugs. On the opening inspection, the inspector will "walk test" the system to ensure that there are no areas within the prescription department uncovered by the alarm. For example, if an inspector can stand in a corner of a bay and move his arms without setting off the alarm, the alarm will not pass. In most cases, more than one sensor is necessary to provide complete coverage.

Regulations require that the Inspection Division receive two weeks notice of an inspection date. It is your responsibility to ensure that your pharmacy is ready to be inspected on the date assigned. If you have delays, which will prevent you from being ready on the assigned inspection date, please let the Board of Pharmacy (804/662-9911) know as soon as possible. The inspector would rather reschedule than make a "wasted" trip for a pharmacy that is not ready. Failure to notify the Board that a facility is not ready for inspection on an assigned date will result in a reinspection fee of $150.

The person listed as pharmacist-in-charge (PIC) should be present at the opening inspection. If the PIC will not be available, he should so notify the Board and ensure that another Virginia licensed pharmacist is present. If deficiencies are noted on the opening inspection, drugs may not be stocked and the permit will not be issued until the PIC assures the Board that the deficiencies have been corrected and the Board gives approval.

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PIC Responsibilities

This document is intended to assist a new pharmacist-in-charge (PIC) as a reminder of some of the responsibilities, and some "do's" and "don'ts". It is not intended to be a comprehensive list of all responsibilities and is not intended to negate individual responsibility of any other pharmacist practicing at the location. ***Pharmacists should not be fearful that, by merely being the PIC of a pharmacy, they will be the subject of Board action for circumstances which are beyond their control.*** *The Board will not hold a PIC responsible for violations of law or regulation which are attributed to another pharmacist or which are solely the fault or responsibility of the owner.*

New Pharmacies:

- If becoming PIC of a new pharmacy, you must be present at the opening inspection of the pharmacy. If you are not able to be present at the opening, you must notify the Board prior to the date of the inspection with the reason why you are not able to be present.

- Make sure at least 24 hours prior to a scheduled opening that the pharmacy is ready for inspection, i.e. all enclosures to the prescription department in place with appropriate locks on entrances, all counters and shelving in place, hot and cold running water working, temperature control system functional, refrigerator working and at proper temperature with monitoring thermometer, all minimum equipment in place, and alarm system functional and fully protects the prescription department. If the new pharmacy will not be ready, you or the owner should notify the inspector as soon as it is known in order that they do not make an unnecessary trip. If the inspector is not notified and the pharmacy cannot reasonably be inspected, a $150 reinspection fee will be assessed upon reinspection.
- If any deficiencies are noted on the opening inspection, as the PIC, you must personally notify the Board of corrections made prior to a permit being issued. Therefore, you should personally inspect any corrections to be sure they have been made properly before contacting the Board.

Upon taking over responsibility as PIC:

- You are not a PIC until the Board approves your signed application. Make sure when you sign an application to be a PIC that you are not still on record with the Board as being a PIC for more than one other pharmacy. Once you are approved as PIC, the Board will issue a pharmacy permit in your name. This is your permit. It must be displayed where the public can read it. If you do not receive the permit within two weeks of sending in the application call the Board and check on the status (804)-662-9921. All pharmacy permits expire on 12/31 annually. Be sure that the permit is renewed each year.

- A PIC is required to be in "full and actual charge of the pharmacy" and "fully engaged in the practice of pharmacy at the location designated on the application". Never agree to sign a pharmacy permit application as PIC unless you intend to meet the requirement of being fully engaged in practice at that pharmacy.

- Take an incoming change of PIC inventory of all Schedule II – V controlled substances upon your takeover as PIC. If the pharmacy is a new pharmacy, you record a zero inventory on the opening date. Always remember to sign and date the inventory and indicate whether it was taken at opening or closing of business. If you take the inventory with the outgoing PIC, both must sign the inventory and so indicate that it is both the incoming and outgoing inventory.

- Verify that every pharmacist working at your pharmacy holds a current license to practice pharmacy. Licensure can be verified by calling the Board at (804) 662-9911 or if you know the license number or social security number of the individual, you may call (804) 662-7636 for automated verification.

- Verify that every pharmacy technician working at your pharmacy holds a current registration or there is documentation on site showing enrollment in a Board approved training program for not more than 9 months.

- You are responsible for ensuring the practice of pharmacy in this pharmacy is in overall compliance with laws and regulations. You are not responsible for individual actions of practicing pharmacists. You should review pharmacy security equipment and procedures to ensure that it meets requirements, such as functional locks on enclosures, functional alarm systems, and access to keys and alarm restricted to pharmacists practicing at the location, including any emergency key kept in compliance with current regulations. Also review record keeping systems to make sure they meet current requirements and that staff pharmacists are aware of their responsibilities.

- Notify the Board of any theft or unusual losses of drugs as soon as discovered.

- Notify the Board of any known violation of law or regulation on the part of another individual in your pharmacy or of any inability to have known deficiencies corrected.

Upon leaving as PIC:

- Take an outgoing change of pharmacist-in-charge inventory of all Schedule II-V controlled substances. Take a **copy** with you. Once you leave, you cannot ensure that the pharmacy will maintain it. If you are denied an opportunity to take this inventory or take a copy of the record, immediately report it to the Board. This inventory is for your protection and an owner who attempts to prevent you from doing this is in violation of regulations. The owner may elect to have someone present with you when you take the inventory.

- As you terminate your position as PIC, remove the pharmacy permit and return it directly to the Board office with a statement that you are not longer PIC and the effective date of the termination of position. Do not leave it on the wall. Do not return it to a corporate or district office or a district manager. It is your permit and your responsibility to return it to the Board immediately. For your protection, we would suggest that you return it by certified mail, return receipt requested.

From Code of Virginia, Drug Control Act

Article 2.
Permitting of Pharmacies

§ 54.1-3404. Inventories of controlled substances required of certain persons; contents and form of record.

A. Except as set forth in subsection G, every person manufacturing, compounding, processing, selling, dispensing or otherwise disposing of drugs in Schedules I, II, III, IV or V shall take a complete and accurate inventory of all stocks of Schedules I through V drugs on the date he first engages in business. If there are no controlled substances on hand at that time, he shall record this fact as part of the inventory. An inventory taken by use of an oral recording device shall be promptly reduced to writing and maintained in a written, typewritten or printed form. Such inventory shall be made either as of the opening of business or as of the close of business on the inventory date.

B. After the initial inventory is taken, every person described herein shall take a new inventory at least every two years of all stocks on hand of Schedules I through V drugs. The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory.

C. The record of such drugs received shall in every case show the date of receipt, the name and address of the person from whom received and the kind and quantity of drugs received, the kind and quantity of drugs produced or removed from process of manufacture, and the date of such production or removal from process of manufacture. The record shall in every case show the proportion of morphine, cocaine, or ecgonine contained in or producible from crude opium or coca leaves received or produced.

D. The record of all drugs sold, administered, dispensed, or otherwise disposed of, shall show the date of selling, administering, or dispensing, the name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were sold, administered or dispensed, and the kind and quantity of drugs. Any person selling, administering, dispensing or otherwise disposing of such drugs shall make and sign such record at the time of each transaction. The keeping of a record required by or under the federal laws, containing substantially the same information as is specified above, shall constitute compliance with this section, except that every such record shall contain a detailed list of any drugs lost, destroyed or stolen, the kind and quantity of such drugs, and the date of the discovery of such loss, destruction or theft. The form of records shall be prescribed by the Board.

E. Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board. If the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedule I through V drugs.

Within 30 days after the discovery of a loss of drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.

F. All records required pursuant to this section shall be maintained completely and accurately for two years from the date of the transaction recorded.

G. Each person authorized to conduct chemical analyses using controlled substances in the Department of Forensic Science shall comply with the inventory requirements set forth in subsections A through F; however, the following substances shall not be required to be included in such inventory: (i) controlled substances on hand at the time of the inventory in a quantity of less than one kilogram, other than a hallucinogenic controlled substance listed in Schedule I of this chapter; or (ii) hallucinogenic controlled

substances, other than lysergic acid diethylamide, on hand at the time of the inventory in a quantity of less than 20 grams; or (iii) lysergic acid diethylamide on hand at the time of the inventory in a quantity of less than 0.5 grams. Further, no inventory shall be required of known or suspected controlled substances that have been received as evidentiary materials for analyses by the Department of Forensic Science.

(1970, c. 650, § 54-524.56; 1972, c. 798; 1978, c. 833; 1979, c. 435; 1980, c. 203; 1982, c. 278; 1988, c. 765; 1998, c. 105; 2004, c. 51; 2005, cc. 868, 881.)

§ 54.1-3432. Supervision by pharmacist.

Every pharmacy shall be under the personal supervision of a pharmacist on the premises of the pharmacy.

(Code 1950, § 54-478; 1958, c. 551; 1970, c. 650, § 54-524.51; 1988, c. 765.)

§ 54.1-3433. Certain advertising and signs unlawful.

It shall be unlawful for any place of business which is not a pharmacy as defined in this chapter to advertise or to have upon it or in it as a sign the words, "pharmacy," "pharmacist," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled" or any like words indicating that drugs are compounded or sold or prescriptions filled. Each day during which such advertisement appears or such sign is allowed to remain upon or in such place of business shall constitute a separate offense under this section. Upon consultation with the Department of Historic Resources, the Board may grant an exception from this section for such signage on an historic building that formerly housed a drugstore or pharmacy if that building is individually listed as a Virginia Historic Landmark, a contributing property in a Virginia Historic Landmark District, or determined to be eligible for listing by the Department of Historic Resources, provided that the signage relates to the historic character of the building.

(Code 1950, § 54-477; 1970, c. 650, § 54-524.49; 1988, c. 765; 2005, c. 97.)

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the Director or his authorized agent shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All permits shall expire on December 31 of each year.

Every pharmacy must be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Each day during which a person is in violation of this section shall constitute a separate offense.

(1970, c. 650, § 54-524.31; 1972, c. 798; 1976, c. 614; 1977, c. 302; 1980, c. 288; 1983, c. 286; 1986, c. 207; 1988, cc. 445, 765; 1994, c. 299; 1998, c. 470; 2000, c. 135.)

§ 54.1-3434.01. Notice of pharmacy closing; change of ownership; penalty.

A. Prior to the closing of a pharmacy for more than one week, the owner shall either (i) post a conspicuous notice at least thirty days prior to the anticipated closing or (ii) mail a notice, at least fourteen days prior to the anticipated closing, to every current pharmacy customer having refill authority. Each notice posted or mailed pursuant to this section shall indicate the date of such closing, if available, and the name of the pharmacy to which prescriptions and other required prescription dispensing records and individual patient records will be transferred unless patients indicate their preference to the contrary. The Board of Pharmacy shall promulgate regulations providing for a definition of "closing of a pharmacy" and exceptions to the requirements of this section.

B. Upon any change of ownership of a pharmacy, regardless of how such change may be effectuated, the prescription dispensing records and other patient records for at least two years immediately prior to the change of ownership, shall be transferred, in accordance with Board regulations, to the new owner in a manner to ensure the confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records and the continuity of pharmacy services at substantially the same level as that offered by the previous owner.

Refusing to process a request for the prescription dispensing records and other patient records tendered in accordance with law or regulation shall constitute a closing and the requirements of this section shall apply. Such refusal may constitute a violation of § 54.1-111 A 9, depending on the circumstance.

(1992, c. 667; 1994, c. 668; 1998, c. 470.)

§ 54.1-3434.02. Automated drug dispensing systems.

A. Hospitals licensed pursuant to Title 32.1 or Title 37.1 may use automated drug dispensing systems, as defined in § 54.1-3401, upon meeting the following conditions:

1. Drugs are placed in the automated drug dispensing system in a hospital and are under the control of a pharmacy providing services to the hospital;

2. The pharmacist-in-charge of the pharmacy providing services to the hospital has established procedures for assuring the accurate stocking and proper storage of drugs in the automated drug dispensing system and for ensuring accountability for and security of all drugs utilized in the automated drug dispensing system until the time such drugs are removed from the automated drug dispensing system for administration to the patients;

3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;

4. Adequate security for automated drug dispensing systems is provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii) complying with federal and state regulations on prescribing and dispensing controlled substances, (iii) maintaining patient confidentiality, and (iv) assuring compliance with the requirements of this section;

5. Accountability for drugs dispensed from automated drug dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to the hospital;

6. Filling and stocking of all drugs in automated drug dispensing systems shall be performed under the direction of the pharmacist-in-charge. The task of filling and stocking of drugs into an automated drug dispensing system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy. The pharmacist stocking and filling the automated drug dispensing system or the pharmacist-in-charge, if the automated drug dispensing system is stocked and filled by a registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the automated drug dispensing system.

B. Drugs placed into and removed from automated drug dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy.

C. The pharmacist-in-charge in a pharmacy located within a hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for (i) periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems, and (ii) reviewing the operation and maintenance of automated drug dispensing systems. This monitoring shall be reviewed by a pharmacist while on the premises of the hospital and in accordance with the pharmacist-in-charge's procedures and the Board of Pharmacy's regulations.

D. The Board of Pharmacy shall promulgate regulations establishing minimum requirements for random periodic inspections and monthly audits of automated drug dispensing systems to assure the proper storage, security, and accountability of all drugs placed in and removed from automated drug dispensing systems and for reviewing the operation and maintenance of automated drug dispensing systems.

(1999, c. 750; 2004, c. 140.)

PART III. PHARMACIES.

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

C. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall take a complete and accurate inventory of all Schedule II through V controlled substances on hand and shall immediately return the pharmacy permit to the board. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board, returning the permit, and taking the required inventory. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

D. An application for a permit designating the new PIC shall be filed with the required fee on a form provided by the board within 14 days of the original date of resignation or termination of the PIC. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline, unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

18VAC110-20-111. Pharmacy technicians.

A. Every pharmacy that employs or uses pharmacy technicians shall maintain a site-specific training program and manual for training pharmacy technicians to work at that pharmacy. The program shall include training consistent with that specific pharmacy practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used at the pharmacy in performing technician duties, and pharmacy calculations consistent with the duties at that pharmacy.

B. Every pharmacy shall maintain documentation of successful completion of the site specific training program for each pharmacy technician for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed pharmacy technicians shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

C. Every pharmacy that employs or uses a person enrolled in an approved pharmacy technician training program pursuant to §54.1-3321 D of the Code of Virginia shall allow such person to conduct tasks restricted to pharmacy technicians for no more than nine months without that person becoming registered as a pharmacy technician with the board. Every pharmacy using such a person shall have documentation on site and available for inspection showing that the person is currently enrolled in an approved training program.

18VAC110-20-120. Special or limited-use pharmacy permits.

For good cause shown, the board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and method of operation, hours of operation, schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing pharmacist control must accompany the application.

3. The issuance and continuation of such permits shall be subject to continuing compliance with the conditions set forth by the board.

18VAC110-20-121. Innovative program approval.

A. An informal conference committee of the board may approve an innovative or pilot program in accordance with §54.1-3307.2 of the Code of Virginia upon receipt of an application and fee specified in 18 VAC 110-20-20.

B. If the informal conference committee determines that an inspection is necessary to adequately consider an application, it may require that the applicant pay a fee specified in 18 VAC 110-20-20 to cover the cost of the inspection.

C. If the informal conference committee determines that a technical consultant is necessary in order for the board to make an informed decision on approval of a program, the applicant shall pay a consultant fee, not to exceed the actual cost of the consultation.

D. In the initial order granting approval of a program, the informal conference committee shall set the approval period with a schedule for submission of required reports and outcome data. The frequency of required reports shall not exceed four times a year.

E. The informal conference committee shall determine the appropriate fee for continued approval of the program based on the requirements for review and monitoring. Such renewal fee shall not exceed $200 per approval period.

18VAC110-20-130. Pharmacy closings; going out of business; change of ownership.

A. At least 14 days prior to the date a pharmacy closes in accordance with §54.1-3434.01 of the Code of Virginia or goes out of business, the owner shall notify the board. The proposed disposition of all Schedule II through VI drugs, prescription dispensing records, patient information records, and other required records shall be reported to the board. If the pharmacy drug stock and records are to be transferred to another licensee, the owner shall inform the board of the name and address of the licensee to whom the drugs and records are being transferred and the date of transfer.

B. Exceptions to the public notice as required in §54.1-3434.01 of the Code of Virginia and the notice required in subsection A of this section shall be approved by the board and may include sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the pharmacy is not able to meet the notification requirements of § 54.1-3434.01, the owner

shall ensure that the board and public are properly notified as soon as he knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

C. In the event of an exception to the notice as required in §54.1-3434.01 of the Code of Virginia and in subsection A of this section, the PIC or owner shall provide notice as far in advance of closing as allowed by the circumstances.

D. At least 14 days prior to any change in ownership of an existing pharmacy, the owner shall notify the board of the pending change.

1. Upon any change in ownership of an existing pharmacy, the prescription dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of pharmacy services.

2. The previous owner shall be held responsible for assuring the proper and lawful transfer of records on the date of the transfer.

3. The format of the prescription dispensing records which are transferred to a new owner shall comply with the requirements of Chapter 34 (§54.1-3400 et seq.) of Title 54.1 of the Code of Virginia, and this chapter. Failure to comply with this chapter during a change in ownership shall be deemed to be a closing of the existing pharmacy for which the existing pharmacy owner shall be required to provide notice to the board and public in accordance with §54.1-3434.01 of the Code of Virginia and subsection A of this section.

18VAC110-20-135. Change of hours in an existing pharmacy.

The owner of the pharmacy shall be responsible for providing notice for a change in the hours of operation to the public and to the board in accordance with § 54.1-3434 of the Code of Virginia unless the change is necessitated by emergency circumstances beyond the control of the owner, or unless the change will result in an expansion of the current hours of operation. If the pharmacy is not able to post the changes 14 days in advance as required by § 54.1-3434, the owner shall ensure that the board is notified as soon as he knows of the change and disclose the emergency circumstances preventing the required notification.

18VAC110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.

A. Any person wishing to open a new pharmacy, engage in the acquisition of an existing pharmacy, change the location of an existing pharmacy, move the location or make structural changes to an existing prescription department, or make changes to a previously approved security system shall file an application with the board.

B. In the acquisition of an existing pharmacy, if prescription records are to be accessible to anyone for purposes other than for continuity of pharmacy services at substantially the same level offered by the previous owner or for the necessary transfer of prescription records, the owner of the pharmacy acquiring the records shall disclose such information in writing to each patient 14 days prior to the acquisition. Such release of prescription records shall be allowed only to the extent authorized by §32.1-127.1:03 of the Code of Virginia.

C. The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.

1. Pharmacy permit applications which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

2. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

3. At the time of the inspection, the dispensing area shall comply with 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180, and 18VAC110-20-190.

4. If an applicant substantially fails to meet the requirements for issuance of a permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18 VAC 110-20-20 prior to a reinspection being conducted.

D. Drugs shall not be stocked within the proposed pharmacy or moved to a new location until approval is granted by the inspector or board staff.

18VAC110-20-150. Physical standards for all pharmacies.

A. The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

B. Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to the effective date of this chapter.

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

D. The entire area of the location of the pharmacy practice, including all areas where drugs are stored shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet U.S.P.-N.F. specifications for drug storage.

E. The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary record keeping.

F. A sink with hot and cold running water shall be within the prescription department.

G. Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department, if the pharmacy stocks such drugs.

18VAC110-20-160. Sanitary conditions.

A. The entire area of any place bearing the name of a pharmacy shall be maintained in a clean and sanitary manner and in good repair and order.

B. Adequate trash disposal facilities and receptacles shall be available.

18VAC110-20-170. Required minimum equipment or resources.

The PIC shall be responsible for maintaining the following:

1. A current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy.

2. A set of Prescription Balances, sensitive to 15 milligrams, and weights or an electronic scale if the pharmacy engages in dispensing activities that require the weighing of components.

3. Other equipment, supplies, and references consistent with the pharmacy's scope of practice and with the public safety.

18VAC110-20-180. Security system.

A device for the detection of breaking shall be installed in each prescription department of each pharmacy. The installation and the device shall be based on accepted burglar alarm industry standards, and shall be subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The device shall be maintained in operating order and shall have an auxiliary source of power.

3. The device shall fully protect the prescription department and shall be capable of detecting breaking by any means when activated.

4. Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy, except for access by other persons in accordance with 18VAC110-20-190 B 2, and the system shall be activated whenever the prescription department is closed for business.

5. This chapter shall not apply to pharmacies which have been granted a permit prior to the effective date of this chapter provided that a previously approved security alarm system is in place, that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and provided further that a breaking and loss of drugs does not occur.

6. If the prescription department was located in a business with extended hours prior to the effective date of this chapter and had met the special security requirements by having a floor to ceiling enclosure, a separately activated alarm system shall not be required.

7. This section shall not apply to pharmacies which are open and staffed by pharmacists 24 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the PIC or owner must immediately notify the board and have installed within 72 hours a security system which meets the requirements of subdivisions 1 through 4 of this section.

18VAC110-20-190. Prescription department enclosures; access to prescription department.

A. The prescription departments of each pharmacy shall be provided with enclosures subject to the following conditions:

1. The enclosure shall be constructed in such a manner that it protects the controlled drug stock from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty.

2. The enclosure shall be of sufficient height as to prevent a person from reaching over to gain access to the drugs.

3. Entrances to the enclosed area must have a door with no more than a six-inch gap from the floor and which is at least as high as the adjacent structure. The requirement for a maximum six-inch gap shall not apply to those pharmacies in existence prior to February 3, 1999, with the exception of any pharmacy which experiences a related diversion or theft.

4. Doors to the area must have locking devices which will prevent unauthorized entry in the absence of the pharmacist.

B. The door keys or other means of entry and alarm access code to the dispensing areas shall be subject to the following requirements:

1. Only pharmacists practicing at the pharmacy and authorized by the PIC shall be in possession of any keys to or other means of opening the locking device on the door to such enclosure, or to the alarm access code.

2. The pharmacist may place a key other means of opening the locking device and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault within the pharmacy or other secured place. This key or code shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with subsection D of this section. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency keys or access codes to the prescription department.

C. The prescription department is restricted to pharmacists who are practicing at the pharmacy. Interns, pharmacy technicians, and other persons designated by the pharmacist may be allowed access by the pharmacist but only during the hours the pharmacist is on duty.

D. Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:

1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;

2. Alternate pharmacist coverage cannot immediately be obtained;

3. The technician is accompanied by a member of the pharmacy's management or administration; and

4. All requirements of subsection E of this section are met.

E. Requirements for entry into the prescription department in the absence of a pharmacist.

1. The requirements for prescriptions awaiting delivery in subsection A of 18VAC110-20-200 are followed.

2. Prior to entry into the prescription department, the pharmacy technician shall obtain verbal permission from the PIC or another pharmacist regularly employed by that pharmacy to obtain and use the emergency key or other access and alarm access code and enter the pharmacy.

3. A record shall be made by the pharmacy technician of the entry to include the date and time of entry, the name and signature of the pharmacy technician, the name, title, and signature of the person accompanying the pharmacy technician, the pharmacist's name granting permission to enter and telephone number where the pharmacist was reached; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department.

4. The pharmacy technician shall reseal the key and alarm access code after the pharmacy is re-secured, and the PIC shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.

5. All records related to entry by a pharmacy technician shall be maintained for a period of one year on premises.

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

A. Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a secure place outside of the prescription department and access to the prescriptions restricted by the pharmacist to designated clerical assistants. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy which detail security of the dispensed prescriptions and a method of compliance with counseling requirements of § 54.1-3319 of the Code of Virginia. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription number(s), date of delivery, and the signature of the person receiving the prescription. Such log shall be maintained for a period of one year.

B. Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

C. Safeguards for controlled paraphernalia. Controlled paraphernalia shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

D. Expired drugs; security. Any drug which has exceeded the expiration date shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

18VAC110-20-210. Disposal of drugs by pharmacies.

If a PIC wishes to dispose of unwanted drugs, he shall use one of the following procedures:

1. Transfer the drugs to another person or entity authorized to possess or provide for proper disposal of such drugs; or

2. Destroy the drugs by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations. If Schedule II through V drugs are to be destroyed, the following procedures shall apply:

a. At least 14 days prior to the destruction date, the PIC shall provide a written notice to the board office; the notice shall state the following:

(1) Date, time, manner, and place of destruction.

(2) The names of the pharmacists who will witness the destruction process.

b. If the destruction date is to be changed or the destruction does not occur, a new notice shall be provided to the board office as set forth above in subdivision 2 of this section.

c. The actual destruction shall be witnessed by the PIC and another pharmacist not employed by the pharmacy.

d. The DEA drug destruction form shall be fully completed and used as the record of all drugs to be destroyed. A copy of the destruction form shall be retained at the pharmacy with other inventory records.

18VAC110-20-220. General requirements for pharmacies providing radiopharmaceutical services.

A. A permit to operate a pharmacy providing radiopharmaceutical services shall be issued only to a qualified nuclear pharmacist as defined in 18VAC110-20-230. In emergency situations, in the absence of the nuclear pharmacist, he may designate one or more other qualified pharmacists to have access to the licensed area. These individuals may obtain single doses of radiopharmaceuticals for the immediate emergency and shall document such withdrawals in the control system.

B. Pharmacies providing ordinary pharmacy services in addition to radiopharmaceutical services shall comply with all regulations applicable to pharmacies in general. Pharmacies providing only radiopharmaceutical services shall comply with all regulations related to physical standards, sanitary conditions and security.

C. Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided and in compliance with standards and requirements of the Nuclear Regulatory Commission (NRC) and the Virginia Department of Health.

D. Radiopharmaceuticals are to be dispensed only upon an order from a practitioner authorized to possess, use and administer radiopharmaceuticals.

1. Orders shall originate at an institution or healthcare facility licensed to receive and possess radiopharmaceuticals, and must contain all necessary information relative to the radiopharmaceutical, activity, time of calibration, and any special preparation or delivery instructions.

2. Orders for radiopharmaceuticals may be transmitted orally, by fax, or by electronic transmission by an authorized agent of the prescriber. If the fax or electronic transmission of the authorized agent is pursuant to an oral order from the prescriber, the transmitted document need not include the prescriber's signature, but must include the name of the agent.

E. The immediate outside container of a radioactive drug to be dispensed shall also be labeled in accordance with requirements of §54.1-3410.1 B of the Code of Virginia.

F. The immediate inner container shall be labeled with: (i) the standard radiation symbol; (ii) the words "Caution--Radioactive Material"; and (iii) the serial number assigned to the order.
G. The amount of radioactivity shall be determined by radiometric methods for each individual dose immediately prior to dispensing.
H. Nuclear pharmacies may redistribute approved radioactive drugs if the pharmacy does not process the radioactive drugs in any manner nor violate the product packaging.

18VAC110-20-230. Qualification as a nuclear pharmacist.
In order to practice as a nuclear pharmacist, a pharmacist shall possess the following qualifications:
1. Meet Nuclear Regulatory Commission (NRC) standards of training for medically used or radioactive by-product material.
2. Have received a minimum of 200 contact hours of didactic instruction in nuclear pharmacy.
3. Attain a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services, or in a structured clinical nuclear pharmacy training program in an approved school of pharmacy.
4. Submit to the board an affidavit of experience and training meeting the requirements of subdivisions 1, 2 and 3 of this section; documentation of NRC approval as an authorized nuclear pharmacist; or documentation of certification as a nuclear pharmacist by the American Pharmaceutical Association Board of Pharmaceutical Specialties.